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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,823	01/16/2007	Todor N. Mazgalev	03220.0013-US-WO	5247

26294 7590 02/03/2009
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EXAMINER	
RANADE, DIVA	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
02/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,823	MAZGALEV ET AL.	
	Examiner	Art Unit	
	DIVA RANADE	4138	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

2. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

Claim Objections

3. Claim 16 is objected to because of the following informalities: It recites 'tachyarrhythmias' and should be changed to tachyarrhythmia. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-23 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Publication 2004/0002740 to Lee et al.

   a. Claim 1: Lee discloses a system for controlling ventricular rate in a heart of a patient, comprising: a cardiac delivery system ([0020]); and a source of fibroblast cells ([0068] and [0072]) and/or a biopolymer ([0061], [0062], [0063]) coupled to the cardiac delivery system, wherein the delivery system is adapted to deliver a volume of material from the source and into or around the patient's AV node ([0024]-[0028]), and wherein the volume of fibroblast cells and/or a biopolymer when delivered into or around the AV node causes conduction delay and/or modification of conduction pathways ([0020]).

   b. Claim 2: Lee discloses the system wherein the cardiac delivery system further comprises at least one needle cooperating and adapted to fluidly couple the at least one needle to the source of fibroblast cells and/or a biopolymer to deliver the material to or around the AV node via the at least one needle ([0053]).

c. Claim 3: Lee discloses an injector assembly that is adapted to inject the volume of material via the cardiac delivery system and into or around the AV node ([0077]).

d. Claim 4: Lee discloses that the cardiac delivery system comprises a delivery catheter (20) with an elongated body (22) with a proximal end portion (24), a distal end portion (28), and a lumen (32) extending between a proximal port (34) along the proximal end portion and a distal port (38) along the distal end portion; a transeptal delivery sheath (502) ([0184]) having an elongate body with proximal end portion, a distal end portion, and a delivery passageway extending between a proximal port along the proximal end portion and a distal port along the distal end portion, wherein the transeptal delivery sheath is adapted to provide transeptal access into the left atrium of the heart via the delivery passageway, and wherein the delivery catheter is adapted to be delivered through the delivery passageway transeptally into the left atrium to thereby deliver the volume of material to or around the AV node ([0184]).

e. Claims 5 and 6: Lee shows that the cardiac delivery system is capable of being an intracardiac and endocardial delivery system ([0024]-[0029]).

f. Claim 7: Lee shows the cardiac delivery that is capable of being adapted to deliver the volume of material into or around the AV node through a vessel wall of a vessel associated with the cardiac tissue structure ([0027]).

g. Claim 8: Lee shows the system further comprising a kit adapted to prepare autologous cells as the material in an injectable form for delivery with the cardiac delivery system to or around the AV node ([0092]).

h. Claim 9: Lee shows wherein the cardiac delivery system comprises at least one needle that is adapted to inject the material into or around the region of tissue at or around the AV node ([0029]).

i. Claim 10: Lee shows wherein the cardiac delivery system comprises a catheter (20) having an elongated body (22) with a proximal end portion (24), a distal end portion (28), and at least one lumen (32) extending between a proximal port (34) located along the proximal end portion and a distal port (38) located along the distal end portion wherein the proximal port is adapted to couple to a source that contains at least a part of the material (36,10, [0123]).

j. Claims 11 and 12: Lee shows a system which is capable of treating an atrial fibrillation or ventricular tachyarrhythmia. ([0100]).

k. Claim 13: Lee describes a method capable of controlling the ventricular rate in a heart of a patient, which comprises administering an effective amount of a material capable of comprising fibroblast cells and/or a biopolymer to and/or around the patient's AV nodal area ([0066]-[0068] and [0077]).

l. Claims 14-16: Lee shows a conduction delay at the AV node which is capable of reducing the incidence of atrial fibrillation and capable of preventing ventricular tachyarrhythmia ([0100] and [0228]).

m. Claim 17: Lee shows a delivery device having a distal end with an anchor and the delivery device distal end is capable of being anchored to or around the AV node as material is delivered ([0129]).

n. Claim 18: Lee shows the material comprising or fibroblast cells and/or a biopolymer ([0068], [0072], [0061], [0062], [0063]) delivered to or around the AV node at least in part transeptally across the atrial septum ([0026]) using a transeptal delivery sheath ([0184]).

o. Claim 19: Lee shows that the fibroblast cells are autologous ([0086]).

p. Claim 20: Less discloses wherein the material comprises of one or more biopolymers ([0078])

q. Claim 21: Lee discloses that the biopolymers are selected from the group consisting of fibrin, collagen, alginate, and precursors and/or derivatives thereof, and combinations of two or more thereof ([0078]).

r. Claim 22: Lee shows that the biopolymer recruits fibroblast cells ([0079]).

s. Claim 23: Lee shows wherein the fibroblast cells and/or a biopolymer are administered in at least one injection ([0040]).

t. Claim 30: Lee shows that there are two or more injections ([0077]) and each injection comprises fibroblast cells, a biopolymer, or fibroblast cells in combination with a biopolymer ([0064]).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication 2004/0002740 to Lee et al.

u. Claims 24-26: Lee discloses that at least one injection must occur ([0080]) but lacks that a range of 1-100 injections may occur as in claim 24-26. However, if more material needed to be injected than is possible with one injection it would be obvious to one skilled in the art during the time of the invention to inject the patient as needed per treatment.

8. Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication 2004/0002740 to Lee et al in view of U.S. Patent 5,660,850 to Boss Jr.

v. Claims 27-29: Lee mentions the use of fibroblast cells but does not mention the number of cells per injection. Boss mentions in his method that the number of cells that can be suspended can include up to one billion cells in 1 ml depending on the number and size of the medium or flask. (See Column 5 lines 21-23). Similarly, the amount of biopolymer injected will reflect the capacity of the

injector which may hold 0.1ml to 5ml as in claims 28 and 29. Therefore it would be obvious to one skilled in the art to combine the method of Boss with Lee in order to create an adequate cell suspension for injection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIVA RANADE whose telephone number is (571)270-7456. The examiner can normally be reached on M-F, 7:30-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Melba Bumgarner can be reached on (571) 272-4709. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. R./
Examiner, Art Unit 4138

/Melba Bumgarner/
Supervisory Patent Examiner, Art Unit 4138